K122557

SHANGHAI MOTEX HEATHCARE CO., LTD.
No.369, Jiasong Zhong Road, Huaxin, Qingpu, Shanghai, 201708, China
Telephone: 86-21-5979 9888 Fax: 86-21-23010718

II. 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

2.1. General Information Establishment

- Manufacturer: **Shanghai Motex Healthcare Co., Ltd.**
- Address: No.369, Jiasong Zhong Road, Huaxin, Qingpu, Shanghai, 201708, China
- Owner Number: **9041164**
  Registration Number: **9615978**
- Contact Person: Dr. Jen, Ke-Min
  E-mail: ceirs.jen@msa.hinet.net Tel: 886-3-5208829 ; Fax: 886-3-5209783
- Date Prepared: August 1, 2012

Device

Proprietary Name: Motex Powder-free Nitrile Surgical Gloves Item 6610 White
Motex Powder-free Nitrile Surgical Gloves Item 6610 Green
Motex Powder-free Nitrile Surgical Gloves Item 6710 Green

- **Common Name:** Surgeon's glove
- **Classification Name:** Surgeon's glove
- **Product Code:**

OCT 0 3 2013

Regulation Number: KGO, Class I, 878.4460

2.2. Safety and Effectiveness Information

- **Predicate Device:**
  Claim of Substantial Equivalence (SE) is made to Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating **(K102500)**
- **Device Description:**
  Motex Powder-free Nitrile Surgical Gloves are made of synthetic rubber. They are sterilized by radiation, and intended for be used in surgery for patient and user.
- **Device Characteristics:**
  Single use only.
  Not made with natural rubber latex.
- **Technological Characteristics:**
  Motex Powder-free Nitrile Surgical Gloves characteristics are summarized below compared to ASTM and ISO standards to the predicate device:

Characteristic	Standard
Dimensions	ASTM D 3577-09e1
Physical Properties	ASTM D 3577-09e1
Freedom from Holes	ASTM D 3577-09e1
Water leak testing	ASTM D 5151:2006
Residual powder testing	ASTM D 6124-06
Water extractable protein testing	ASTM D 5712-10
Biocompatibility	ISO10993-10/-12
Sterilization Validation	ISO11137-1/-2

- **Powder Residual:**

  Surgeon's gloves meet powder level requirements for "Powder-free" designation per ASTM D6124, Standard test method for residual powder on medical gloves. The results generated values will below 2mg of residual powder per glove.

- **Clinical Data:**

  Not applicable.

- **Indications for Use:**

  A surgeon's glove is a sterile and for single use device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded.

- **Substantial Equivalence (SE)**

  A claim of substantial equivalence is "Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating" (K102500). Both of the subject device and predicate device have the same indications for use, material composition with Nitrile, meet the performance tests by ASTM D3577, powder residual by ASTM D6124, and also completed the biocompatibility, sterilization validation test reports. The major differences are the subject devices have different colorants for two items, including 6610_White, 6610_Green, and 6710_Green; and the specifications are 6~8.5 size. In addition, the predicate device is made with neoprene and coated with nitrile, while the subject device is made solely with nitrile rubber. These differences are not relating to the safety or effectiveness aspects. Thus they are substantially equivalent.

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Comparison to Legally Marketed Device

Similarity:

Comparison Feature	Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating **(K102500)**	Motex Powder-free Nitrile Surgical Gloves **(K122557)**
Indications For Use	Those powder-free sterile surgeon's gloves are a disposable devices made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination in the environments within hospitals and other healthcare facilities.	A surgeon's glove is a sterile and for single use device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded.
Prescription/OTC Device	Over-the-Counter Use	Same
Product code	KGO, Class I, 878.4460	KGO, Class I, 878.4460
Intended Use	Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating are a disposable device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination in the environments within hospitals and other healthcare facilities.	Sterile disposable devices made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.
Material Composition	Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Powder-Free Nitrile Surgical Gloves
Performance Test for Pinhole, Dimensions, and Physical properties	Meets ASTM D3577	Same
Powder Residual	Results generated values below 2mg of residual powder per glove	Meets ASTM D6124 Same
Biocompatibility	Gloves are non-irritating. Gloves do not display any potential for sensitization.	Meets ISO10993-10/-12 Same
Sterilization Method	Irradiation Sterilization	Meets ISO11137-1/-2 Same

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Difference:

Product Trade Name	Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Motex Powder-free Nitrile Surgical Gloves Item: 6610_White, 6610_Green, and 6710_Green
Device Design	Made with neoprene and coated with nitrile; and it is powder-free and sterile.	Made solely with nitrile rubber; and it is powder-free and sterile.
Color of the Devices	No prior information	White and Green
Specification size	No prior information	6, 6.5, 7, 7.5, 8, 8.5
Water Extractable Protein Testing	No prior information	Meets ASTMD5712

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

Shanghai Motex Healthcare Company, Limited
Dr. Jen, Ke-Min
Official Correspondent
369 Jiasong Zhong Road
Huaxin, Qingpu, Shanghai 201708
CHINA

Re: K122557
Trade/Device Name: Motex Powder-free Nitrile Surgical Gloves Item 6610 White
Motex Powder-free Nitrile Surgical Gloves Item 6610 Green
Motex Powder-free Nitrile Surgical Gloves Item 6710 Green

Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: September 18, 2013
Received: September 25, 2013

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

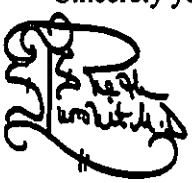
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (K) Number (If Known): K122557

Device Name: Motex Powder-free Nitrile Surgical Gloves Item 6610 White
Motex Powder-free Nitrile Surgical Gloves Item 6610 Green
Motex Powder-free Nitrile Surgical Gloves Item 6710 Green

Indications for Use:

A surgeon's glove is a sterile and for single use device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded.

Prescription Use _____ AND/OR Over the Counter Use √
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.10.02 17:29:07 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) K122557